IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

TRISTA KILDOW,

Plaintiff,

v.

BREG, INC., a California corporation,

Defendant.

Civ. No. 10-12-AA

OPINION AND ORDER

AIKEN, Chief Judge:

Plaintiff filed suit alleging products liability and negligence after a medical device known as a "pain pump" was used to administer local anesthetics into her shoulder joint after arthroscopic surgery. Plaintiff seeks economic, non-economic, and punitive damages. Defendant Breg, Inc. (Breg) was the alleged manufacturer and distributer of the pain pump.

Breg now moves for summary judgment on plaintiff's claims. Breg argues that plaintiff's claims are barred by the relevant

statute of limitations, or alternatively, that plaintiff cannot establish that Breg knew or had reason to know of any inherent danger associated with pain pump use prior to plaintiff's surgery. Breg also argues that plaintiff cannot prove that Breg's alleged failure to warn caused her injuries, or that she is entitled to punitive damages. The motion is denied.

BACKGROUND

Pain pumps are medical devices used to administer prescribed amounts of pain medication directly to a certain area of the body. The marketing, labeling, and sale of pain pumps are regulated by the Food and Drug Administration (FDA). The FDA classifies medical devices into three types: Class I, Class II, and Class III. 21 U.S.C. § 360c. Breg's pain pumps are Class II devices. As with other brands of pain pumps, Breg's pain pumps are prescription devices sold to and prescribed by licensed physicians.

Prior to marketing a new Class II medical device, a manufacturer must obtain Premarket Approval (PMA) for the device unless an exception applies. See 21 U.S.C. §§ 360c, 360e. As pertinent to this case, the "substantial equivalent" exception permits the marketing of a new Class II device through the premarket notification process, commonly known as the "510(k)" notification process. Id. §§ 360c(f); 360(k). "Under the 510(k) process, if the Class II device is deemed 'substantially equivalent' to a pre-existing device with prior clearance, 'it can

be marketed without further regulatory analysis.'" PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 925 (9th Cir. 2010) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996)). "In other words, that device receives '510(k) clearance' and can be put on the market." Id. The 510(k) notification process is much less rigorous than the PMA process and requires no additional testing of the device. Id.; Medtronic, 518 U.S. at 478-79.

At all relevant times, Breg's pain pumps were marketed through the 510(k) notification process for general surgical use at the "inter-operative" site. See Young Decl., Ex. 2 (Bates No. 6556.0088) (doc. 42, filed under seal). Breg and other pain pump manufacturers had attempted to obtain clearance through the 510(k) process to market pain pumps for the specific indication of orthopedic use and/or use in the or joint cavity. According to plaintiff, Breg attempted on three occasions to obtain 510(k) clearance for specific indications of orthopedic and intra-articular use. Young Decl., Ex. 2 (Bates No. 6556.0011, 6556.0179) Ex. 3; Ex. 6 (Bates No. 5396.0012) (doc. 42, filed under seal); Ex. 7 (Bates No. 6574.0010).[1] However, the FDA determined that a substantially equivalent predicate device with this specific use

[1]Breg disputes that it actively sought 510(k) clearance for orthopedic or intra-articular use, explaining that such terms were included in a comparison table Breg provided to the FDA and were not submitted as proposed indications. See Breg's Reply Mem., pp. 4-5. However, all factual inferences must be construed in plaintiff's favor.

did not exist and did not give clearance to market the pain pumps for use in the joint space. Young Decl., Ex. 9. Rather, the FDA gave clearance for the general indication "intra-operative" use and instructed Breg to remove any references to intra-articular or orthopedic use from materials submitted to the FDA. Young Decl., Ex. 3; Ex. 6 (Bates No. 5396.0097, 5396.0099); Ex. 7 (Bates No. 6574.0022-.0023); Ex. 9. Plaintiff maintains that Breg nonetheless continued to market and sell its pain pump for use directly in the joint space, in violation of FDA regulations. Breg denies these allegations.

On July 23, 2003 and March 22, 2004, plaintiff underwent arthroscopic surgery on her right and left shoulders, respectively. Plaintiff's surgeon used a Breg pain pump device to administer local anesthetics following surgery. Plaintiff's surgeon, Dr. Sedgewick, placed the pain pump catheter directly into her shoulder joints to deliver the prescribed pain medication. Subsequently, plaintiff developed glenohumeral chondrolysis, a very rare condition involving the rapid and permanent destruction of articular cartilage in the shoulder joint.

On January 6, 2010, plaintiff filed suit. Plaintiff maintains that Breg was on notice that the use of pain pumps to deliver pain medication directly to the shoulder joint could cause harm, and that Breg nonetheless marketed its pain pumps for such use and failed to warn physicians that pain pumps had not been cleared for

such use by the FDA, rending the pain pump a defective product.

DISCUSSION

Breg moves for summary judgment on several grounds. Breg first argues that plaintiff's claims are time-barred, because she reasonably could have discovered the causal relationship between her injury and Breg's pain pump more than two years prior to the filing of her lawsuit. Or. Rev. Stat. § 30.905(1). Breg emphasizes that plaintiff was diagnosed with degenerative joint disease and loss of cartilage in April and May 2006, and that chondrolysis litigation was ongoing and advertised over the internet as early as 2007. Thus, Breg maintains that plaintiff reasonably should have discovered the basis for her claims prior to January 6, 2008.

"[T]he discovery accrual rule provides that a plaintiff's claim against a particular defendant accrues when (1) the plaintiff knows, or a reasonable person should know, that there is enough chance that the defendant had a role in causing the plaintiff's injury to require further investigation; and (2) an investigation would have revealed the defendant's role." T.R. v. Boy Scouts of Am., 344 Or. 282, 296, 181 P.3d 758 (2008). Here, Breg cites no evidence showing or suggesting that plaintiff was advised that her cartilage deterioration was caused by a Breg pain pump or even related to her surgical procedures. Even though plaintiff received a diagnosis of degenerative joint disease and loss of cartilage in

2006, Breg cites no definitive evidence that she was informed as to the potential source or cause of her disease, or that she had reason to know that a defective product, as opposed to some other factor, was the cause of her shoulder pain. Breg appears to argue that plaintiff should have made inquiry about the cause of her shoulder pain, including a search of the internet. "Whether a plaintiff is subject to a duty to inquire about facts that might trigger a statute of limitations, however, is itself a question of fact." Cole v. Sunnyside Marketplace, LLC, 212 Or. App. 509, 521, 160 P.3d 1 (2007). Thus, I deny summary judgment on this ground.

Breg next argues that plaintiff fails to present any evidence that, at the time of her surgery, the scientific or medical community had reason to know of any risk associated with using pain pumps to administer local anesthetics directly to the joint space. Breg contends that under Oregon law, its duty to warn is limited to the dangers of which it knew or reasonably should have known. See McEwen v. Ortho. Pharm. Corp., 270 Or. 375, 385-86, 528 P.2d 522 (1974) (drug manufacturer has duty "of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know"); Benjamin v. Wal-Mart Stores, Inc., 185 Or. App. 444, 454, 61 P.3d 257 (2002) (a warning is required "if the seller 'has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge,' of the presence of the danger")

(quoting Restatement (Second) of Torts § 402A, comment j); see also Or. Rev. Stat. § 30.920(3) (statute to be construed in accordance with Restatement (Second) of Torts, § 402A, comments a through m). Thus, Breg maintains that because it did not know or have reason to know of any association between pain pump use and chondrolysis as of July 2003 or March 2004, plaintiff cannot prevail on her products liability or negligence claims.[2] I disagree and find issues of material fact preclude summary judgment.

Though not overwhelming, plaintiff presents some evidence that Breg knew or should have known of toxicity concerns associated with the administration of local anesthetics directly into the joint area. Plaintiff submits the declaration of an orthopedic surgeon who asserts that prior to 2000, existing medical and scientific knowledge indicated that "continuous exposure to foreign solutions could be harmful" to articular cartilage and would have put a medical device manufacture on notice that the continuous infusion of anesthetics for one to two days "would likely risk injury to the cartilage." Trippel Decl., Ex. A, pp. 5-13 (citing articles attached to Trippel Decl.); see also Parisian Decl., Exs. A, B.

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[2]Plaintiffs' counsel has taken the position that a strict products liability claim based on failure to warn does not require that the manufacturer knew or should have known of the alleged risk of harm but only that the device was unreasonably dangerous without an adequate warning. Phillips v. Kimwood Machine Co., 269 Or. 485, 498, 525 P.2d 1033 (1974). Given the questions of fact regarding Breg's actual or constructive knowledge, I need not address this issue for purposes of Breg's motion.

Such evidence must be considered in the context of Breg's regulatory and marketing efforts and the lack of a specific indication for the use of pain pumps in the joint space, the FDA's determination that no predicate device established the efficacy and safety of such use, and Breg's continued promotion of the pain pumps for use in the joint space without a specific indication cleared by the FDA. See Pence Decl., Ex. A.

Construing all inferences in favor of plaintiff, this evidence is sufficient to create a material issue of fact as to whether Breg should have known or anticipated that continuous infusion of local anesthetics directly into the shoulder joint was toxic or could cause damage. Monroe, 2011 WL 534037, at *22-23; Hamilton v. Breg, Inc., 2011 WL 780541, at *3-5 (D. Ohio Jan. 20, 2011); Koch v. Breg, Inc., 2010 WL 5301047, at *2-4 (D.S.D. Dec. 20, 2010). It is not incumbent on plaintiff to show that Breg should have known of the specific injury or damage - chondrolysis - alleged caused by the use of the pain pumps.

I recognize that several courts have held otherwise and found that any danger from intra-articular pain pump use was "not knowable" prior to 2005 or 2006. Rodriguez v. Stryker Corp., 2011 WL 31462, at *8 (M.D. Tenn. Jan. 05, 2011); see also Krumpelbeck v. Breg, Inc., 759 F. Supp. 2d 958, 974 (S.D. Ohio 2010); Pavelko v. Breg, Inc., 2011 WL 782664, at *5-6 (D. Colo. Feb. 28, 2011); Phillippi v. Stryker Corp., 2010 WL 2650596, at *3 (E.D. Cal. July

1, 2010); Meharg v. I-Flow Corp., 2010 WL 711317, at *3-4 (S.D. Ind. Mar. 1, 2010). I respectfully disagree with those decisions and instead find this question appropriate for the trier of fact. It may well be that plaintiff's evidence at trial fails to show by a preponderance that Breg had reason to know of the risks associated with pain pump use and chondrolysis. As noted by one district judge, "[t]he medical evidence that pain pumps could cause chondrolysis was at best fragmentary at the time" of plaintiff's surgery. Hamilton, 2011 WL 780541, at *3. On a motion for summary judgment, however, all inferences must be construed in favor of plaintiff. So construed, genuine issues of material fact remain.

Breg also contends that plaintiff cannot show any alleged failure to warn by Breg caused her injury. Breg emphasizes that plaintiff's surgeon, Dr. Sedgewick, testified at deposition that he could not remember a Breg sales representative instructing him as to the placement for the pain pump catheter. Young Decl., Ex. 62 (Sedgewick Depo., p. 55). However, Dr. Sedgewick's testimony must be considered as a whole with evidence of Breg's marketing strategies, including marketing the pain pumps for use in the joint space, and the effect of such marketing on physician practices and training. See Young Decl., Ex. 35 (Bates 1928.0015) (doc. 42, filed under seal); Ex. 37 (Bates 2835.0016) (doc. 42, filed under seal); Ex. 38 (Bates 2836.0003-.0004, 2836.0008); Ex. 39 (Bates Nos. 50983, 50985, 50992); Ex. 40 (Bates Nos. 53071); Ex. 62

(Sedgewick Depo., pp. 92-94).

Finally, Breg moves for summary judgment regarding plaintiff's prayer for punitive damages. As found in other pain pump cases, plaintiff presents little evidence that Breg had actual knowledge of harm resulting from the use of pain pumps in the joint space as of July 2003 or March 2004, such that Breg acted with "malice" or "reckless and outrageous indifference to a highly unreasonable risk of harm" and with "conscious indifference to the health, safety and welfare of others" by marketing its pain pumps for intra-articular uses. Or. Rev. Stat. § 31.730(1); Andor v. United Air Lines, Inc., 303 Or. 505, 517, 739 P.2d 18 (1987) (punitive damages "are a penalty for conduct that is culpable by reason of motive, intent, or extraordinary disregard of or indifference to known or highly probable risks to others"). However, as explained above, the extent of Breg's knowledge is a question of fact, and I decline to grant summary judgment at this time.

CONCLUSION

Breg's Motion for Summary Judgment (doc. 30) is DENIED.

IT IS SO ORDERED.

DATED this 11th day of July, 2011.

Ann Aiken
United States District Judge